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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,211	01/30/2002	Klaus Schumann	3868-0103P	9968
2292	7590	04/26/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,211	<b>Applicant(s)</b> SCHUMANN ET AL.	
	<b>Examiner</b> Isis Ghali	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1/30/01</u> . | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' IDS, filed 01/30/2001; amendment, filed 01/29/2004; and request under 1.114, filed 03/01/2004.

Claims 6-10 have been canceled, and claims 11-14 have been added and included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/01/2004 has been entered.

#### ***Specification***

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

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As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,115,913 ('913) in view of WO 96/34633 ('633).

Claim 11 recites a method of preventing pressure-sensitive adhesive (PSA) from leaking out in cold flow during storage of PSA-substrate that sealed in a bag to protect against loss of active substance, the substrate comprising backing, matrix of PSA or provided with PSA layer on its application surface, the method comprising the step of providing a carrier layer on the PSA made of two sections that are overlapping. One of the carrier layer sections is wider than the other by an amount of overlap (claim 12). One of the carrier layer sections is wider than half the width dimension of an undivided carrier layer by the amount of half the overlap (claim 13); and the region of the overlap is positioned centrally or eccentrically (claim 14).

US '913 teaches a method for increasing the storage stability and protection from cold flow of PSA in a transdermal device, and protection of volatile components from evaporation. The transdermal device is packed and sealed in a bag comprising substrate sections that are PSA or rendered PSA on their surfaces and protected by support layer on one side and carrier layer on the other side (abstract; col.1, lines 1-47).

The reference teaches method for prevention of cold flow by providing means to prevent migration of PSA by manipulating the carrier layer.

The difference between the present invention and the cited reference is the structure of the carrier layer that prevents the migration of the PSA.

WO '633 teaches a dressing set (substrate sections) that keeps the active agent in a reservoir at a constant level for a prolonged storage time (abstract; page 2, last paragraph). The dressing set comprising a backing; a reservoir containing at least one pharmaceutically active substance; a pressure sensitive adhesive surface layer on one of the surfaces of the backing; and more than one peel stripes (abstract). The peel stripes extend beyond the edges of the dressing and are overlapping (page 4, paragraph 3, figure 2). It is evident from figure 2 that both carrier layer sections are overlapping in the center of the dressing (claim 14). Figure 2 also shows that one carrier section is wider than the other by the amount of the overlap (claim 12). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side (claim 13). In any events, applicants are not claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a transdermal device having PSA layer sealed in a bag for prolonged storage and prevention of cold flow as disclosed by US '913, and replace the carrier layer that have been manipulated to protect against migration of PSA by the carrier layer having two overlapping sections disclosed by WO '633, motivated by the desire of WO '633 to keep the active agent in the reservoir at a constant level for a prolonged storage time ( as also desired by applicants), with reasonable expectation to achieve a transdermal device comprising PSA layer that is sealed in bag and having carrier layer with two overlapping sections that has increased stability of the drugs in the patch and prevent PSA leak from the device during storage.

### ***Response to Arguments***

6. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

IG



**ISIS GHALI**  
**PATENT EXAMINER**